

**REMARKS**

Claims 17-37 are all the claims pending in the application.

**Rejection under 35 USC 102**

The Examiner maintains the rejection of claims 17-19 over the alleged applicant's admissions at page 2 of the specification.

Applicants respectfully traverse the rejection for the reasons of record and additionally in view of the following.

Applicants submit that the Examiner improperly considers that because the claimed yeast strains were deposited, they were known and available to the public as of the date of the deposit. However, it is well established that the mere reference to a deposit in the application does not necessarily mean that the deposited biological material is available, as stated in MPEP §2404.01. That is, the mere fact that Applicants have indicated that a deposit was made does not mean that the deposited strains were made available to the public with unrestricted access so as to make them known and useable by the general public as asserted by the Examiner. To the contrary, the Statements of Availability indicate and the deposit rules allow for "restrictions on availability" during the pendency of the application.

In the instant case the deposit was made under the Budapest Treaty. Rule 11.3 of the Budapest Treaty provides that deposited samples may not be provided to the public (*i.e.*, to third parties not having the express authorization of the depositor) before publication of a patent application referring to the deposit. Since the publication of the instant application took place 18 months after the priority date, the soonest the deposited material could have been made available to the public is 18 months after the priority date.

Moreover, the deposit was made by the Applicant (Lesaffre et compagnie) on behalf of all the inventors, i.e., the same inventive entity and therefore, is not the work of another. The work of the same inventive entity may not be considered prior art against the claims unless it falls under one of the statutory categories, and the deposit does not qualify as prior art under section 102.

Finally, the Examiner has no legal basis for maintaining that the Declaration signed by the inventors is insufficient to establish that all inventors contributed to the claimed invention. The fact that various embodiments of the invention are claimed is not relevant to this issue.

In view of the above, the rejection under 35 U.S.C. §102 is improper. Withdrawal of the rejection is respectfully requested.

**Rejection under 35 USC 103**

Claims 17-41 stand rejected under 35 U.S.C. §103 as allegedly being unpatentable over Satoshi et al in view of Hill.

The Examiner deems that Satoshi et al investigates the hybridization process for generating hybrid yeast strains that are highly resistant to high sugar content in bread.

In the previous Response, Applicants already explained that:

- (1) there would be no reasonable expectation of success in developing the very *Saccharomyces cerevisiae* strains which are claimed, because the method used in Satoshi et al and Hill for producing yeast strains is very different from the method used in the present application for producing the claimed strains; and
- (2) there would be no reasonable expectation of success either in developing other *Saccharomyces cerevisiae* strains which would have the same properties as the claimed strains,

because Satoshi et al and Hill do not teach how to obtain strains with as high a tolerance to sugar as the presently claimed strains; there is no suggestion either in Satoshi et al and Hill as to how to obtain strains having a higher tolerance to sugar than those of Satoshi et al/Hill and thus as to how to get closer to the presently claimed strains.

The Examiner replies that “*absence evidence of criticality regarding the present process claims and given that Satoshi et al meets the requirements of the claimed composition, Satoshi et al clearly meets the requirements of present claims 17-22, 24-27, 29-33, 35-41*”.

However, the skilled person would not obtain the very claimed strains based on Satoshi et al and Hill, even if the references were combined.

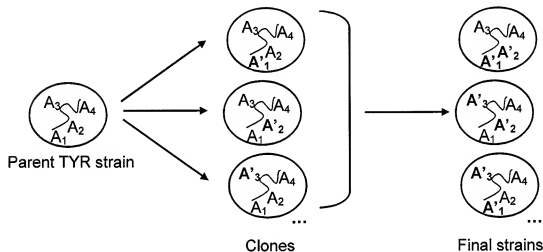
First of all, claims 17-19 relate to three very specific strains. In Satoshi et al, all strains are derived from a single strain, the so-called TYR strain. There is absolutely no evidence that the genetic or phenotypic features of the TYR strain are similar to those of the three very specific strains of claims 17-19 (or even to those of the strains which are derived from these three specific strains and are the subject-matter of claims 20 and following). Therefore, the statement that “*Satoshi et al meets the requirements of present claims 17-22*” etc., is utterly unfounded.

Notwithstanding the above, there is indeed a critical difference between the process used in Satoshi et al and the process used in the claimed invention for obtaining yeast strains. According to Satoshi et al, clones are produced starting from the single parent TYR strain, and then the clones are hybridized to yield the final strains. In contrast, the strains of the present invention were obtained by cross-hybridizing a number of commercial strains (used in the bread-making industry) or strains from public collection centers known to have osmotolerance property and/or low sensitivity to mould inhibitors (see paragraph 16 of the application).

In Satoshi et al, the genetic material of the obtained strains is substantially the same as that of the single initial strain TYR, although rearranged in a random manner, whereas the strains obtained according to the present invention have a genetic material which is the result of random combinations of various genetic materials from a diversity of initial strains.

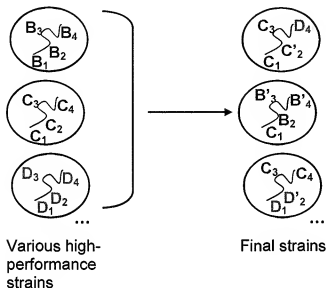
The following two simple drawings will illustrate this difference in the obtained products.

The process taught by Satoshi et al may be schematically illustrated as follows:



In the process taught in Satoshi et al, the parts of the genetic material of the parent TYR strain are symbolized by the letters  $A_1$ ,  $A_2$ ,  $A_3$ ,  $A_4$ . At the first stage of the process, some mutations  $A'_1$ ,  $A'_2$ , etc., appear in the clones. Then, the mutated parts of the TYR genetic material are randomly combined in the final strains which are obtained through cross-hybridization of the clones.

This stands in sharp contrast with the process of the invention leading to the claimed strains, which can be illustrated as follows:



In the process of the present invention, the starting material does not involve a single parent strain but rather a number of strains (commercial strains or strains from public collections). The genetic material of these strains (respectively symbolized by B<sub>1</sub>-B<sub>2</sub>-B<sub>3</sub>-B<sub>4</sub>, C<sub>1</sub>-C<sub>2</sub>-C<sub>3</sub>-C<sub>4</sub>, etc.) is necessarily much more diversified than that of the TYR clones in document Satoshi et al. This genetic material may then partly be subjected to some mutations (for instance C'<sub>2</sub>, B'<sub>3</sub>, etc.) and is randomly redistributed in the final strains, owing to hybridization techniques.

As a result, the process used in the invention makes it possible to obtain a much greater variety of final strains than Satoshi et al. For instance, it would be impossible to obtain a strain having a mixed genetic material such as D<sub>1</sub>-D'<sub>2</sub>-C<sub>3</sub>-C<sub>4</sub> using the process of Satoshi et al. In Satoshi et al, the genetic material of the final strains only comprises parts that are substantially

identical to those of the parent TYR strain (*e.g.*, A<sub>1</sub>, A<sub>2</sub>) and parts that are slight variations relative to the parent TYR strain (*e.g.*, A'<sub>3</sub>, A'<sub>4</sub>).

In addition, it should be noted that the starting material in Satoshi et al (namely the TYR strain) is a freeze-tolerant yeast but is not supposed to be particularly tolerant to sugar in dough, whereas the starting material according to the present invention is made up of various strains already having a high performance in terms of osmotolerance.

Consequently, it cannot be reasonably expected that the variants of the TYR strains obtained in Satoshi et al are the same as the claimed strains.

Even assuming *arguendo* that the skilled person combined the teaching of Satoshi et al with that of Hill, he/she would not arrive at the claimed invention. Indeed, Hill teaches how to propagate yeast in the presence of organic acids but does not disclose any method of producing new yeast strains. Therefore, the skilled person would not modify the protocol of Satoshi et al for producing new strains, based on the teaching of Hill. He/she would still start with the TYR strain as a single parent strain and be content with the cross-hybridized clones.

Moreover, the skilled person would not have obtained nor reasonable expected to obtain other strains having properties similar to those of the claimed strains, based on Satoshi et al and Hill.

The Examiner argues that the strains of Satoshi et al are more efficient than those of the claimed invention in terms of tolerance to sugar in dough. Applicants respectfully disagree and submit that the Examiner has not provided a reasonable technical basis for this assertion.

In Satoshi et al, the sweet dough contains 30% of sugar relative to the flour, or 16.2% sugar relative to the total weight of the dough; on the other hand, according to the claimed

invention, the PT<sub>2</sub> reference test provides a sugar amount of 40% relative to the flour, or 19.6% relative to the total weight of the dough.

The Examiner notes that the sugar-to-yeast ratio is 10 in the sweet dough recipe of Satoshi et al vs. 4.4 in the PT<sub>2</sub> reference test of the invention. The Examiner concludes that the strains of Satoshi et al are 2.5 times more efficient than the claimed strains. The latter conclusion is flawed because what matters for the metabolism of the yeast is the concentration of sugar in the environment rather than the sugar-to-yeast ratio<sup>1</sup>.

Since there is a higher concentration of sugar in the PT<sub>2</sub> reference test of the present invention than in the sweet dough recipe of Satoshi et al, the Examiner should reach the opposite conclusion, namely that the strains of the claimed invention are more effective than those of Satoshi et al.

In fact, when one looks at the actual performance of the yeast in the presence of sugar, an exact comparison between the strains of Satoshi et al and those of the claimed invention may not be made. As rightly noted by the Examiner, the controls and criteria for assessment are not the same.

However, it can still be noted, based on Table 4 in Satoshi et al, that the strains obtained through the hybridization process do not behave significantly better on sweet dough than the starting TYR strain and than the reference strains KY 5649 and KY 5650. The maximum increase in CO<sub>2</sub> production in the hybridized strains is only 4% relative to the reference strains.

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<sup>1</sup> For instance, considering a composition A containing 1% yeast and 1% sugar, and a composition B containing 10% yeast and 10% sugar, the yeast of composition B will be much more severely impacted by the sugar than the yeast of composition A, although the sugar-to-yeast ratio is the same.

In contrast, the claimed invention achieves a significant improvement of as high as 25% to 35% in terms of proof time, relative to the reference strain NCYC 996 (see Table 2), even though the conditions are harsher for the yeast, the sweet dough of the present invention containing more sugar than the sweet dough of Satoshi et al.

Therefore, one of ordinary skill in the art would consider that this comparison is an indication that the claimed strains perform better in the presence of sugar than the strains of Satoshi et al. There is no basis however, for the Examiner's assertion that the strains of Satoshi et al perform better (or even as well as) the claimed strains, because there is not the slightest evidence of this on the record.

In conclusion, the method for developing sugar-tolerant strains according to the invention is more efficient than the method taught in Satoshi et al. According to the claimed invention, the starting material is made up of strains that are already sugar-tolerant, which is not the case of the starting material in Satoshi et al (the TYR strain); besides, a much higher degree of recombination of the genetic material is achieved owing to the invention than in Satoshi et al, because the starting material is much more diversified.

It is thus perfectly logical that the claimed strains, which were obtained through a more efficient process than that of Satoshi et al, perform better on sweet dough. There is absolutely no evidence of the contrary in Satoshi et al.

The deficiencies of Satoshi et al discussed above are not cured by Hill, since Hill does not deal with the production of new sugar-tolerant strains.

Therefore, all pending claims are non-obvious over Satoshi et al combined with Hill.

Consequently, Applicants respectfully request withdrawal of the obviousness rejection.

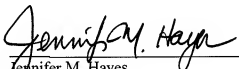


**Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

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